CLAIMS

1. A method for preparing theophylline sustained release particles comprising

heating a matrix base material containing a polyglycerol fatty acid ester, theophylline and ethyl cellulose to give a liquefied mixture; and

granulating the liquefied mixture by spray-cooling.

2. The method according to Claim 1 comprising

heating a matrix base material containing a polyglycerol fatty acid ester, theophylline and ethyl cellulose to give a liquefied mixture;

granulating the liquefied mixture by spray-cooling to obtain spherical core particles; and

applying fine powder to the core particles by fusion coating.

3. The method according to Claim 2, wherein the core particles have a theophylline content of about 8 to about 50 wt.% and an ethyl cellulose content of about 0.01 to about 5 wt.%, and the fine powder is applied to the core particles in an amount of about 5 to about 50 parts by weight per 100 parts by weight of the core particles.

4. The method according to Claim 2 or 3, wherein the core particles have an average particle diameter of 250 μm or less, and the theophylline sustained release particles obtained by fusion coating have an average particle diameter of 450 μm or less.

5. The method according to any one of Claims 1-4, wherein the polyglycerol fatty acid ester is a polyglycerol fatty acid half ester.

6. The method according to any one of Claims 1-5, wherein the polyglycerol fatty acid ester is a triglycerol behenic acid half ester.

7. The method according to Claim 1 or 2, wherein the matrix base material further contains a glycerol fatty acid ester.

8. The method according to Claim 7, wherein the glycerol fatty acid ester is at least one member selected from the group consisting of a glycerol behenic acid ester and glycerol stearic acid ester.

9. The method according to Claim 8, wherein the glycerol fatty acid ester is a glycerol behenic acid ester.

10. The method according to any one of Claims 2-9, wherein the fusion coating is performed using agitation method.

11. The method according to any one of Claims 2-10, wherein the fusion coating is performed at a temperature in the vicinity of the melting point or the softening point of the matrix base material.

12. The method according to any one of Claims 1-11, wherein the matrix base material has a hydroxyl value of about 60 or greater.

13. The method according to any one of Claims 2-12, wherein the fine powder is at least one member selected from the group consisting of talc, magnesium stearate, titanium oxide, ethyl cellulose, calcium stearate and cellulose acetate.

14. The method according to Claim 2 further comprising the step of heat treatment after the fusion coating.

15. The method according to Claim 2 further comprising subjecting the core particles to a heat treatment before the fusion coating.

16. The method according to Claim 14 or 15, wherein the heat treatment is conducted at a temperature from about 40° C to about the melting point or the softening point of the matrix base material.

17. Theophylline sustained release particles obtainable by the method according to any one of Claims 1-16.

18. Particles comprising a matrix base material containing a polyglycerol fatty acid ester, theophylline and ethyl cellulose,

the theophylline and ethyl cellulose being uniformly dispersed throughout the matrix base material.

19. Theophylline sustained release particles each comprising the particle of Claim 18 as nucleus particle and a coating layer comprising a fine powder formed around the nucleus particle

20. The theophylline sustained release particles according to any one of Claims 17-19 having a 2-hour theophylline dissolution rate of about 15 to about 55%, a 4-hour dissolution rate of about 25 to about 70% and a 6-hour dissolution rate of about 50 to about 95%, as measured according to *The Japanese Pharmacopoeia*, 14th Edition, Dissolution Test (2nd Method, Paddle Method) at a stirring speed of 75 rpm using water or a 0.5% aqueous polysorbate 80 solution as test solution.

21. A method for preparing medicament sustained release particles comprising applying a fine powder by fusion coating to core particles containing a pharmacologically active substance and a matrix base material that has a hydroxyl value of 60 or greater and contains a polyglycerol fatty acid ester.

22. The method according to Claim 21 comprising

heating a pharmacologically active substance and a matrix base material that has a hydroxyl value of 60 or greater and contains a polyglycerol fatty acid ester to thereby give a liquefied mixture,

granulating the liquefied mixture by spray-cooling to obtain spherical core particles; and

applying fine particles to the core particles by fusion coating.

23. The method according to Claim 21 or 22, wherein the fusion coating is performed at a temperature in the vicinity of the melting point or the softening point of the matrix base material.

24. The method according to any one of Claims 21-23, wherein the matrix base material has a hydroxyl value of about 80 to about 350.

25. The method according to any one of Claims 21-24 further comprising a heat treatment step after the fusion coating.

26. The method according to any one of Claims 21-24 further comprising subjecting the core particles to a heat treatment before the fusion coating.

27. The method according to Claim 25 or 26, wherein the heat treatment is conducted at a temperature from about 40° C to about the melting point or the softening point of the matrix base material.

28. A method according to any one of Claims 21-27, wherein the polyglycerol fatty acid ester is a polyglycerol fatty acid half ester.

29. The method according to any one of Claims 21-27, wherein the polyglycerol fatty acid ester is a triglycerol behenic acid half ester.

30. Medicament sustained release particles obtainable by the method according to any one of Claims 21-29.

31. Particles comprising a pharmacologically active substance and a matrix base material having a hydroxyl value of 60 or greater and containing a polyglycerol fatty acid ester,

the pharmacologically active substance being uniformly dispersed throughout the matrix base material.

32. Medicament sustained release particles each comprising the particle of Claim 31 as nucleus particle and a coating layer comprising a fine powder and formed around the core particles.